REMARKS

Status of the Claims

Claims 1-26 are in the application.

Claims 1-11 and 23-26 were withdrawn from consideration.

By way of this amendment, claims 12, 20, and 21 have been amended, and claims 1-11 and 23-26 have been canceled. New claims 27-30 have been added.

Upon entry of this amendment, claims 12-22 and 27-30 will be pending.

Summary of the Amendment

Claim 12 has been amended to correct obvious typographical errors and to recite the claim more precisely.

Claims 20 and 21 have been amended to correct obvious typographical errors.

New claims 27-30 have been added in order to recite a series of specific embodiments of the claimed invention including steps that include the testing of the function of the generated oligonucleotides. Support for the amendment appears on pages 9, lines 5-9; the bridging paragraph of pages 15 and 16; and Example 2 on page 32 of the specification.

No new matter has been added.

Claim Objections

Claims 12, 20, and 21 are objected for incorporating alleged informalities including various grammatical errors. Claim 12 has been amended to include the suggested punctuation per the examiner's request. Claims 20 and 21 have been amended to correct an obvious typographical error per the examiner's request. As amended, the claims are more clear. Applicants respectfully request that the objection to claims 12, 20, and 21 be withdrawn.

Claim Rejection Under 35 U.S.C. §112, second paragraph

Claims 12-22 stand rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claims the subject matter which

Applicants regards as the invention. The Office asserts that claim 12 is indefinite because the metes and bounds of the term "loop" cannot be determined from the language of the claims. The Office asserts that claim 12 is also indefinite because the terms "5' end of the distal region" in the context of other elements of step (c). Applicants respectfully disagree, but solely in order to expedite prosecution have amended claim 12 step (b) and step (c) to include the terms "of mRNA" and "of the microRNA" to more clearly recite the invention. The amendments obviate the basis of the rejection.

Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph, as to steps (b) and (c) of claim 12 be withdrawn. One of ordinary skill in the art would easily comprehend what the metes and bounds of the terms mean in light of the plain language of the claims and the relevant disclosure in the specification.

Claim 12 is definite within the meaning of 35 U.S.C. §112. Accordingly, Applicants respectfully request that the rejection of claims 12-22 under 35 U.S.C. §112, second paragraph be withdrawn.

Claim Rejection Under 35 U.S.C. §112, first paragraph

Claims 12-22 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly failing the enablement requirement. The Office asserts that:

> while being enabling for a method of generating a putative microRNA sequence comprising following the steps recited in claim 12, then confirming the existence of this putative microRNA and its corresponding MRE in the target mRNA using an appropriate blotting technique (e.g. Northern blot), then testing the ability of the putative microRNA to inhibit expression of the corresponding mRNA in an in vitro expression assay, does not reasonably provide enablement for generating a microRNA by only performing the calculations and steps recited in claim 12.

(Office Action, page 6). Applicants respectfully disagree.

Applicants note that it is well established that the Office has the initial burden of establishing that a claimed invention does not meet the enablement requirement. The description of the invention is presumed to be enabled and, in order to sustain an enablement rejection under

the first paragraph of 35 U.S.C. § 112, the Examiner must establish doubt in the objective truth of Applicant's assertion that the claimed invention is enabled using reasoning and evidence of those skilled in the art. See, e.g. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). See also M.P.E.P. § 2163.

The Office has failed to set forth any a single reference to support the rejection. The Office has not established that the claimed invention does not meet the enablement requirement. Failing to do so, the burden is not properly shifted to Applicants.

Applicants respectfully urge that the evidence and reasoning in the specification supports the conclusion that one skilled in the art would accept Applicant's assertion that the claims are enabled by the specification. In the absence of any evidence in support of the rejection, Applicants are not required to put forth any evidence. Nevertheless, Applicants submit the following reasoning to support the conclusion that the specification enabling the claimed invention.

The claims recite a method of generating a microRNA. "Generating miRNAs" is defined on page 10 of the specification as creation of a sequence that can bind to an MRE. The definition includes embodiments performed *in silico* (page 10, line 7) and embodiments performed by oligonucleotide synthesis (page 10, line 9). The fact that the there are no steps in the claim that include confirming the presence and function of the miRNA is irrelevant in the context of the meaning of the terms "generating a microRNA."

The claims are enabled. Applicants respectfully request that the rejection of claim 12-22 based upon 35 U.S.C. §112, first paragraph, be withdrawn.

Conclusion

Claims 12-22 and 27-30 are in condition for allowance. A notice of allowance is earnestly solicited. Applicants invite the Examiner to contact the undersigned at 610.640.7852 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully submitted,

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